Claim Rejections:

Claims 1-33 are all the claims pending in the application, and currently all of the claims remain rejected. Applicant thanks the Examiner for indicating that the rejections under 35 U.S.C. § 101 and 112, 2nd paragraph have been withdrawn.

35 U.S.C. § 103(a) Rejection – Claims 1-33:

Claims 1-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the previously applied Usher reference (claims 1-16 and 17-33), and as being unpatentable over Usher in view of Mioduszewski (claims 8, 14 and 27). In view of the following discussion, Applicant respectfully disagrees.

As an initial matter, Applicant acknowledges the Examiner's comments regarding the signed statement by Professor Klaus Bock, and submits that the statement was filed with Applicant's previous response. However, Applicant files herewith an additional copy for the Examiner's review. Further, Applicant incorporates herein Applicant's previous arguments and discussions originally set forth in Applicant's Amendment filed March 3, 2004.

Turning now to the above rejection, Applicant again notes that the starting material for the Usher process is dextran (containing aldehyde groups only in the terminal of the molecule) or hydrogenated dextran (where the aldehyde groups of the molecule have been converted to alcohol groups).

In the present application the starting material is dextran.

The first step in the Usher process is oxidation using periodate to transform dextran or hydrogenated dextran to molecules containing additional newly formed aldehyde groups in the intermediate glycosyl groups.

The first step in the present application is a partial hydrogenation, where the terminal aldehyde groups on a fraction of the molecules are converted to alcohol groups.

The second step in the Usher process may be a second oxidation step, whereby all aldehyde groups (optional originally present at the terminus of the molecules as well as the newly formed aldehyde groups in the intermediate glycosyl groups) are converted to carboxylic acid groups. This material is reacted with ferric hydroxide.

Alternatively, the second step in the Usher process is a reaction with cyanide, however this embodiment is less relevant for the present application.

The second step in the present application is an oxidation step whereby all unreacted terminal aldehyde groups present after the partial hydrogenation are converted to carboxylic groups. This material is used in the reaction with ferric hydroxide.

However, the material that ultimately is used in the reaction with ferric hydroxide in the Usher process will be a dextran derivative wherein all molecules have intermediate pairs of carboxylic acid groups and optionally a terminal carboxylic acid group.

In contrast, in the present invention, the material that ultimately is used in the reaction with the ferric hydroxide in the actual application is a dextran derivative, wherein a fraction of the molecules contains one terminal carboxylic group and the remaining fraction of the molecules contains no carboxylic acid groups.

It is, therefore, submitted that the iron dextran products prepared according to the present application is completely different from the products disclosed in Usher and that the teachings in Usher, in no way, would lead the skilled person to the present invention.

Moreover, Mioduszewski merely teaches that addition of citric acid or citrates may confer increased stability to iron containing compounds. However, Mioduszewski does not disclose any teaching or suggestion that, if it were combined with Usher the resultant combination would lead to the present invention.

In support of the above discussion, Applicant submits herewith a signed statement by Professor Klaus Bock, from the Department of Chemistry of the Carlsberg Laboratory, Denmark, which is an internationally recognized research institution. As evidenced by Professor Bock's statement (comparing Usher with the subject matter of the present application, i.e. WO 00/30657), and in view of the corresponding exhibits, "the overall conformation of [the] product [of the present application] will be completely different from the product produced by [Usher]. Professor Bock's Statement, page 2.

In addition to the above discussion (initially set forth in Applicant's march 3, 2004 Amendment, Applicant submits that the disclosure of Usher teaches away from the present invention. Specifically, in Usher, at col. 30, lines 40-50, Usher states:

> While we do not wish to be bound by any theory as the reason for our ability to obtain an improved iron dextran with a high stable iron content, it is believed that the presence of a plurality of carboxylic acid groups positioned upon intermediate units of the dextran polymer molecule provide complexing sites for the ferric hydroxide which permit the association of greater amounts of the ferric hydroxide molecules to a higher degree than in complexes of the prior art. Col. 30, lines 40-50.

In view of the foregoing passage, Applicant submits that one of ordinary skill in the art would recognize and believe that Usher et al. believed that the beneficial properties of the compounds, could be assigned to the presence of "a plurality of carboxylic acid groups positioned upon intermediate units of dextran polymer molecule". *See* passage above. In view of at least this passage, the skilled artisan would not be motivated to optimize the dextrans, disclosed by Usher, in a way where "a plurality of carboxylic acid groups positioned upon intermediate units of dextran polymer molecule" would be lost, because Usher teaches that this would abandon the benefits set forth and described by Usher et al.

Applicant, therefore, submit thats Usher et al. teach away from the present invention, as Usher et al. teach that the "a plurality of carboxylic acid groups positioned upon intermediate units of dextran polymer molecule" must be present in the dextran molecules in order to obtain the stated benefits.. However, the present invention teaches that no carboxylic acid groups should be present on intermediate units of dextran polymer molecule, and no plurality of carboxylic acid groups should be present in any dextran molecule. Therefore, in the present invention, elements which are considered to be important, in Usher, are omitted.

Thus, in a fundamental sense, the present invention is based on a different understanding of the nature of dextran molecules and iron dextran complexes, as compared to Usher et al. In view of the foregoing, and the statements by Professor Bock, it is submitted that the present invention is not obvious over Usher et al. or the cxombination of Usher and Mioduszewski.

In view of the foregoing, Applicant submits that Usher, either individually or in combination with Mioduszewski, fails to teach or suggest each and every feature of the claims 1

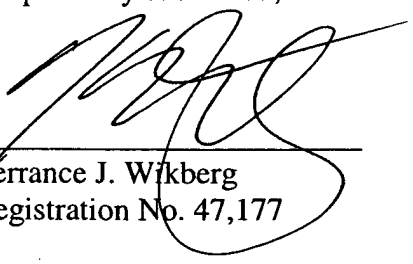
and 9 of the present application. Therefore, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness with respect to these claims, as required under 35 U.S.C. § 103(a). Accordingly, Applicant hereby requests the Examiner reconsider and withdraw the above 35 U.S.C. § 103(a) rejection of claims 1 and 9. Further, as claims 2-8 and 10-33 depend on these claims, Applicant submits that these claims are also allowable, at least by reason of their dependence.

Conclusion:

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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